

Tracking a Submitted Application, Approved Documents and Related Projects

Home Workspace – Approved Tab

The screenshot shows the eResearchM Regulatory Management interface. At the top, it says 'eResearchM REGULATORY MANAGEMENT' and 'Ila Investigator | My Home | Logoff'. Below this is a navigation bar with 'All Submissions', 'IBC', 'Repository Applications', and 'Help'. The main content area is titled 'Home Workspace Ila Investigator' and features a 'Study Staff' button. On the left, there's a sidebar with 'My Roles' (Study Team Member) and 'Create New' options (Study, User, IBC Registration, Repository Application). The main area has a notification about IBC registration changes. Below that are tabs for 'My Inbox', 'In Progress', 'Approved', 'Exempt and Not Regulated', 'Approaching Expiration', and 'Archived'. The 'Approved' tab is active, showing a table of study applications. A filter dropdown is set to 'Name'. The table has columns for Name, PI, State, Type, Last State Change, and ID. Two rows are visible: 'Sample One' and 'Sample Two'. A '1' is placed over 'Sample One' in the original image.

Letter	Tab/Column	Description
A	My Inbox	Submissions only display in My Inbox if an action is required by you.
B	In Progress	All new submissions display in In Progress . Amendment, Continuing Review, and Adverse Event submission display in In Progress prior to approval. Once approved, these submissions can be viewed by accessing the parent study.
C	Approved	Lists study applications that have been Approved .
D	Exempt and Not Regulated	Exempt and Not Regulated applications display in Exempt and Not Regulated .
E	Approaching Expiration	Applications expiring within 90 days display in Approaching Expiration .
F	Archived	Completed or withdrawn studies display in Archived .
G	State	The State column displays the current state of the study.

1. Click the **Name** of the study to open it and view more detail.

Study Workspace

H. The status bar shows the progression the study application has made through the approval process.

I. The **Current State** of the study appears at the top left corner of the workspace.

J. Activities for each study display under **Activities and Correspondence**.

Note: Items listed in **Correspondence** indicate actions that have already taken place. These icons are not active function buttons.

2. Click **See Approval Letter** under Activity to open and view the Approval Letter.

Study Workspace – Documents Tab

K. The **Documents** tab displays all documents related to the study.

L. Documents listed in **Finalized Documents** are consent recruitment materials that have been finalized by Core Office Staff.

M. Links to documents included in the study application by the study team display in **Documents in the Study**.

N. Any linked PAFs display in **Associated Proposals (PAFs)**.

O. **Supporting Documents** uploaded by core staff are other documents added to the application workspace by Core Office Staff.

Study Workspace – Related Projects Tab

Main	Notes	Documents	Related Projects	Projects	Continuing Reviews	AE/ORID	Change Tracking																																														
<p>Links to related Human Subjects Studies (HUMs), Repositories (REPs), and Unfunded Agreements (UFAs) are maintained by IRB staff based on submission evidence (including HUM question 1.1.2) and other input from study teams. Contact the IRB (via Post Correspondence activity) for relationship additions or deletions.</p> <p>Links to Proposal Award Forms (PAFs) are maintained by the study team within the application (initial submission, or amendment).</p> <p>The ID number is a link that will open/display the HUM, REP, UFA, or PAF only for those study team members or reviewers who have applicable view or edit rights. HUM-HUM, HUM-REP, and REP-REP links created in one application display in both linked applications.</p> <p>Related Human Subject Studies (HUM):</p> <table border="1"> <thead> <tr> <th>ID</th> <th>Title</th> <th>PI</th> <th>Application Type</th> <th>State</th> <th>Expiration Date</th> <th>Last Amend Approval Date</th> <th>Relationship Notes</th> </tr> </thead> <tbody> <tr> <td colspan="8">There are no items to display</td> </tr> </tbody> </table> <p>Related Repository (REP) Applications:</p> <table border="1"> <thead> <tr> <th>Repository ID</th> <th>Title</th> <th>PI</th> <th>State</th> <th>Expiration Date</th> <th>Last Amend Approval Date</th> <th>Relationship Notes</th> </tr> </thead> <tbody> <tr> <td>REP00000032</td> <td>Cardiovascular Health Improvement Project (CHIP) Biobank</td> <td>Iris Investigator</td> <td>Approved</td> <td>10/8/2017</td> <td></td> <td></td> </tr> </tbody> </table> <p>Related UFAs:</p> <table border="1"> <thead> <tr> <th>UFA ID</th> <th>Title</th> <th>PI</th> <th>State</th> <th>Category</th> <th>Start Date</th> <th>End Date</th> <th>Relationship Notes</th> </tr> </thead> <tbody> <tr> <td colspan="8">There are no items to display</td> </tr> </tbody> </table> <p>Related PAFs: There are no items to display.</p> <p><small>PAF and UFA data last updated: 10/17/2016 4:04 PM</small></p>								ID	Title	PI	Application Type	State	Expiration Date	Last Amend Approval Date	Relationship Notes	There are no items to display								Repository ID	Title	PI	State	Expiration Date	Last Amend Approval Date	Relationship Notes	REP00000032	Cardiovascular Health Improvement Project (CHIP) Biobank	Iris Investigator	Approved	10/8/2017			UFA ID	Title	PI	State	Category	Start Date	End Date	Relationship Notes	There are no items to display							
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- P. The **Related Projects** tab displays links to all projects related to the study (HUM, REP, UFAs and/or PAFs).